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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,331	06/27/2005	David Fraser Wixey	(1171/42323) Case 150-PCT	5738
279 7590 04/09/2007 Trexler, Bushnell, Giangiorgi, Blackstone & Marr, Ltd. 105 West Adams Street Suite 3600 Chicago, IL 60603			EXAMINER LOPEZ, AMADEUS SEBASTIAN	
			ART UNIT 3771	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/518,331	Applicant(s) WIXEY ET AL.	
	Examiner Amadeus S. Lopez	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/15/04 & 9/21/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The examiner has considered all references disclosed within the Information Disclosure Statement filed on 12/15/2004 and 9/21/2005.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 1113. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 1115, 1160 and 2038. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing

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sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "2034 " has been used to designate both the lower bridge and the lower rim. Further reference character "2012 " has been used to designate both the nasal mask and the hollow body. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

On page 4 in line 8, the word "is" after the word "which" should be deleted.

On page 4 in line 23, the number "6" should be deleted and replaced with the number -- 5 --.

Appropriate correction is required.

Claim Objections

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 15 does not appear to further limit claim 1 since the limitation of claim 15 is fully disclosed in the preamble of claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the nasal bridge region" in line 2 of claim 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "the cheek region" in line 2 of claim 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 4 recites the limitation "the upper lip region" in line 2 of claim 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 is deemed indefinite by the examiner because the applicant claims that the outer region and the middle region comprise "dead space." According to the specification and the figures, the applicant discloses dead space to be empty space which deems the claim indefinite. The applicant can not claim that the inner, middle and outer region comprise nothing or empty space. It is unclear what exactly the applicant is attempting to claim as their invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Scarberry et al (US 2002/0100479).

As to claim 1, Scarberry et al discloses a sealing interface for use with delivery of respiratory gases to a user comprising: an inner sealing member (34 shown in figure 1) an outer sealing member (28 shown in figure 1), wherein the inner sealing member and the outer sealing member are adapted to seal around the facial contours of the user thereby providing a sealed fluid communication to the respiratory tract of the user (see

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an outer sealing member (28 shown in figure 1), wherein the inner sealing member and the outer sealing member are adapted to seal around the facial contours of the user thereby providing a sealed fluid communication to the respiratory tract of the user (see figure 2), and the inner and outer sealing members are at least continuously in contact with each other around the facial contour contacting portions respectively (the two members are continuously in contact with each other around the facial contour contacting portions shown in figure 2).

As to claims 2-4, Scarberry et al discloses a sealing interface wherein the inner sealing member has a cut out region in the nasal bridge region, in the cheek region, and the upper lip portion (labeled in figure 1 shown below).

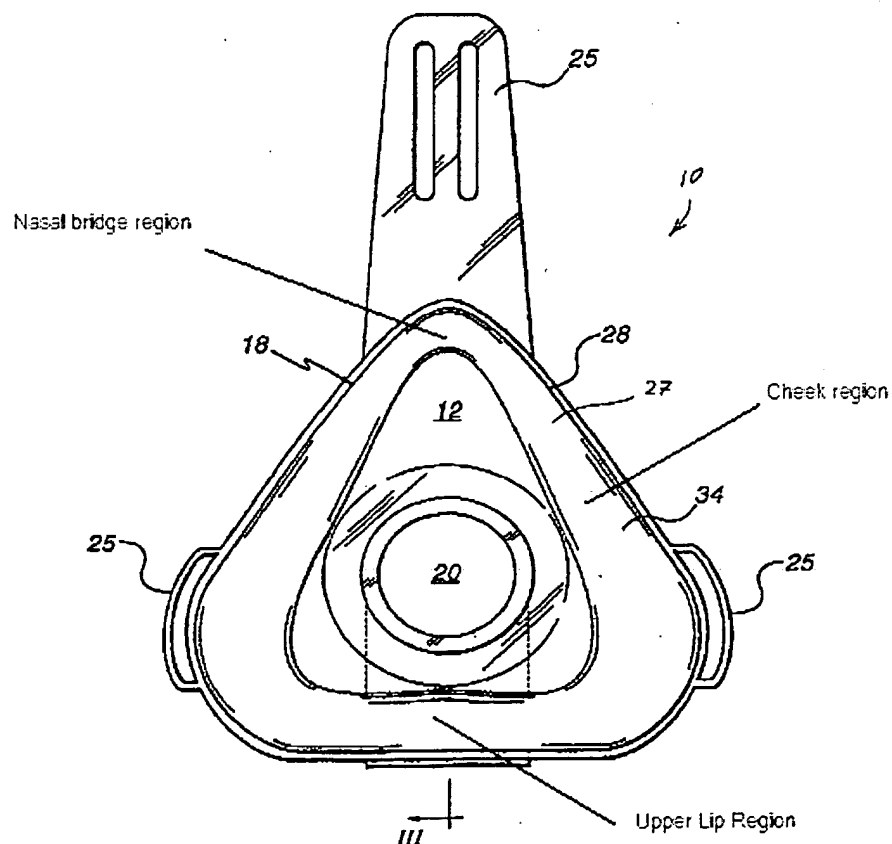


Figure 1

As to claim 5, Scarberry et al discloses a sealing interface wherein the inner sealing member and the outer sealing member are continuously in contact both in use and when not in use around the facial contour contacting region (see figure 1 wherein 28 and 34 are continuously in contact).

As to claim 6, Scarberry et al disclose a sealing interface wherein the inner sealing member and the outer sealing member are continuously in contact all around the inner sealing member (the two members are shown continuously in contact in figures 1 and 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarberry in view of Palkon et al (7007696).

As to claim 7, Scarberry et al discloses a sealing interface with all the limitations of the claim with the exception of wherein the inner sealing member includes a cheek region of the facial contour contacting region wherein the cheek region is concaved to accommodate the cartilages extending away from the middle of the nose of a user. The mask of Palkon includes a cheek region that is chamfered in a concave manner so as to accommodate the cartilages extending away from the middle nose of a user as shown in figure 3. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a cheek region that is concaved to accommodate the cartilages extending away from the middle nose of a user to create a more comfortable and more effective air tight seal against the contours of the user's face as disclosed by Palkon et al.

As to claim 8, Scarberry et al discloses a sealing interface with all the limitations of the claim with the exception of wherein the facial contour contacting portion comprises a nasal bridge region whereby the nasal bridge region is tapered away from the user with respect to the remainder of the facial contour contacting portion. Palkon discloses a mask cushion as shown in figure 2 that comprises a nasal bridge region (38) whereby the nasal bridge region is tapered away from the user with respect to the remainder of the facial contact portion. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the mask of Scarberry to include a nasal bridge section that is tapered away from the user to create a more comfortable and effective air tight seal against the nasal bridge of the user as disclosed by Palkon et al.

As to claim 9, Scarberry et al discloses a sealing interface wherein the nasal bridge region comprises an inner region, a middle region and an outer region whereby in use the inner region is most proximate the user (labeled in figure shown below).

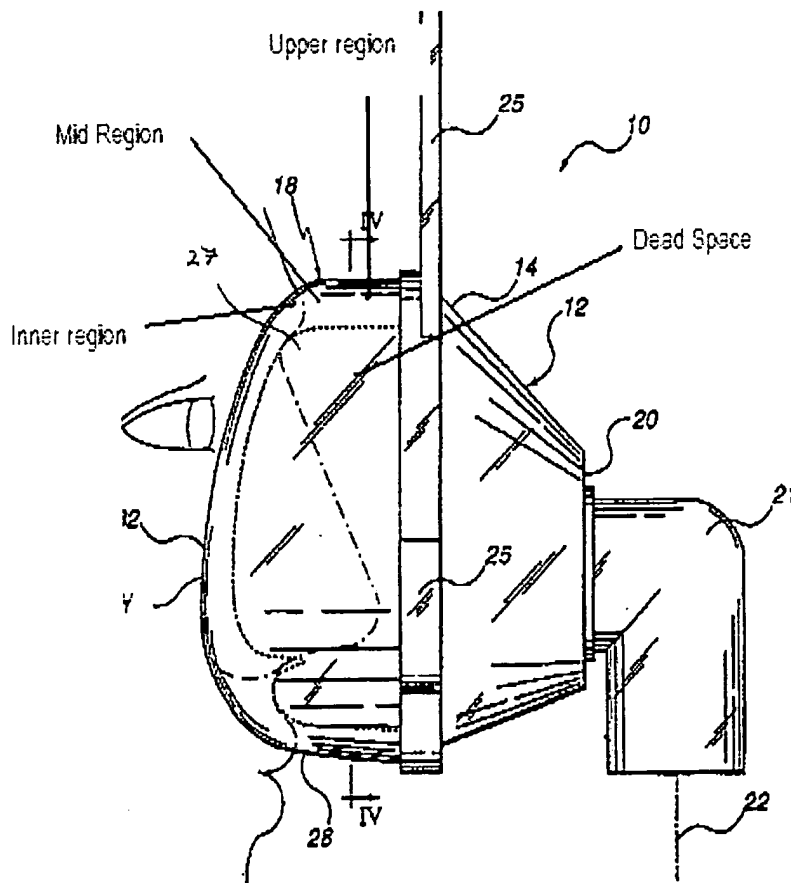


Figure 2

As to claim 10, Scarberry et al discloses a sealing interface 9 wherein the inner region, the middle region and the outer region comprise dead space (figure 2 above shows that the disclosed regions comprise dead space within the mask labeled in the figure).

As to claim 11, Scarberry et al discloses a sealing interface wherein the inner region comprises a flexible resilient member (paragraph [0041] discloses that seal 18 which comprises both inner and outer seals 34 and 28 is "solid, yet highly resilient and self-sustaining compressible") and the middle region and the outer region comprise dead space (figure 2 shows that the disclosed regions comprise deadspace within the mask labeled in figure above).

As to claim 12, Scarberry et al discloses a sealing interface wherein the inner region and the outer region comprise a resilient deformable material (paragraph [0041] discloses that seal 18 which comprises both inner and outer seals 34 and 28 is "solid, yet highly resilient and self-sustaining compressible") and the middle region comprises dead space (figure 2 shows that the disclosed region comprise deadspace within the mask labeled in figure above).

As to claim 13, Scarberry et al discloses a sealing interface wherein the inner sealing member is adapted to follow the concave portion in the cheek region (paragraph [0041] discloses that "the contour of the of sealing surface 34 is performed to closely approximate the surface contour of a user's facial structure, especially in the areas of the bridge of the nose, the cheeks adjacent the nose, the space intermediate the nose and upper lip, and the intervening areas contiguous to these.")

As to claim 14, Scarberry et al disclose a sealing interface wherein the inner sealing member is adapted to contact the cheek region only when in use (it is inherent that the inner sealing member will only contact the cheek region when the mask is in use).

As to claim 15, Scarberry et al discloses a patient interface for delivering respiratory gases to a user including a sealing interface (see figure 2).

Conclusion

The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure to show mask cushion assemblies: US 2004/0118406, US 7107989, US 6357441, US 2003/0019495, US 6112746, and US 6651663.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Amadeus S Lopez

Examiner

Art Unit 3771

March 24, 2007

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4/24/07